REMARKS

Applicant has carefully studied the outstanding Official Action mailed on August 6, 2008. This response is intended to be fully responsive to all points of rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application are respectfully requested.

Claims 1, 4-6, 8-13 and 18 stand rejected under 35 USC §102(b) as being anticipated by Reiley et al. (US 6248110).

Claim 2 stands rejected under 35 USC §103(a) as being unpatentable over Reiley et al. in view of Davison (US 6530926).

Claim 3 stands rejected under 35 USC §103(a) as being unpatentable over Reiley et al. in view of McNamara et al. (US 5147370).

Claims 7 and 16 stand rejected under 35 USC §103(a) as being unpatentable over Reiley et al. in view of Foley et al. (US 6676665).

Claim 14 stands rejected under 35 USC §103(a) as being unpatentable over Reiley et al. in view of Scholten et al. (US 4969888).

Claims 15 and 17 stand rejected under 35 USC §103(a) as being unpatentable over Reiley et al. in view of Cragg (US 2002/0016583).

Applicant respectfully traverses these rejections over Reiley et al. as is now explained.

Examiner relies on Figs. 6 and 7 of Reiley et al. and says Reiley et al. has the elements of claim 1, namely, "a sheath compactor adapted to slide a portion of said sheath along said rod from a first position to a second position, wherein in the first position said sheath is in a non-expanded orientation and in the second position said sheath is in an expanded orientation wherein folds of said sheath expand radially outwards from said outside portion of said rod, wherein said elastomeric sheath surrounds the outside portion of the rod both in the non-expanded and expanded orientations and wherein said folds in the expanded orientation comprise a plurality of crests and troughs".

However, please note that there is a fundamentally difference in structure between Reiley et al. and the instant invention. The alleged folds of the sheath in Fig. 7 of Reiley et al. are a result of *collapsing* the expandable body 56 in the *proximal* direction, as stated in col. 9, lines 46-56: "FIG. 7 shows an alternative technique for filling the cavity. In this technique, the injector tip 90 occupies the cavity 84 while the expandable body 56 is collapsing within the cavity 84. As the body 56 collapses, the tip 90 injects material 96 into the part of the cavity 84 that the collapsing body 56 no longer occupies. The increasing

volume of the cavity 84 not occupied by the collapsing body 56 is thereby progressively filled by an increasing volume of material 96. The presence of the body 56, partially expanded while the tip 90 injects the material 96, serves to compact and spread the injected material 96 within the cavity 84. As filling of the cavity 84 progresses, preferably under fluoroscopic monitoring, the physician progressively retracts the injector tip 90 from the anterior region of the cavity 84, toward the outer guide sheath 72, allowing the material 96 to progressively enter and fill the cavity 84 with the collapse of the body 56."

When expandable body 56 is expanded as in Fig. 6, there are no folds. On the contrary, Reiley et al. teaches away from folds in the expanded position because the expandable body 56 is needed to compact tissue, as in col. 10, line 66 to col. 11, line 18: "For example, expandable bodies 56 with generally elastic properties will exhibit the tendency to backflow or creep into the outer guide sheath 72 during their expansion. It is therefore necessary to internally or externally restrain a body 56 that is subject to creeping, to keep it confined within the interior bone region. In FIG. 6, an exterior sealing element 100 is provided for this purpose. In FIG. 6, the sealing element 100 takes the form of a movable o-ring. The physician advances the o-ring 100 along the catheter tube 50 inside the guide sheath 72 using a generally stiff stylet 102 attached to the o-ring 100. The physician locates the o-ring 100 at or near the distal end 54 of the catheter tube 50 prior to conveying the liquid 82 to expand the body 56. The o-ring 100 is held in place by the generally stiff stylet 102, which provides a counter force to prevent backward movement of the o-ring 100 in the guide sheath 72 as the body 56 expands. The o-ring 100 thereby keeps all or a substantial portion of the generally elastic body 26 confined inside the interior volume 30. The body 56 thereby serves to compact as much of the cancellous bone 32 as possible."

Furthermore in the rejection of claim 2 over Davison, Examiner cites "a vertebral prosthesis that uses a stopper in col. 9, line 58 to col. 10, line 4 for the purpose of protecting the end of the inserted device". This is The passage from Davison is as follows: "As viewed in FIG. 20, the chamber 328 is closed at its upper end by a cap 335. The cap 335 has an opening 336 centered on the axis 314. The opening 336 communicates with the chamber 328. A manually movable internal valve member 340 normally closes the opening and blocks the chamber 328 from communicating with the ambient air surrounding the support arm 300. The valve member 340 is connected to a stem 341, which is also centered on the axis 314. The stem 341 has a knob or button 343 on its end that may be manually depressed to move the stem 341 and valve member 340 downward into the chamber 328. When the

stem 341 and valve member 340 are so moved, the chamber 328 is in communication with the ambient air surrounding the device due to the unblocking of the opening 336".

Applicant respectfully traverses this rejection. This passage is describing the support apparatus and is not a vertebral prosthesis that uses a stopper for the purpose of protecting the end of the inserted device. Also, it is respectfully pointed out that Reiley et al. teaches away from using a stopper at the distal end, because such a stopper would prevent expandable body 56 from expanding beyond the end of the rod to compact tissue as shown in Fig. 6.

In the rejection of claim 3 over McNamara et al., Examiner cites a fastening ring from col. 9. Examiner is undoubtedly referring to the following: "A. In the first technique, the spiral was formed with a fixing ring on its distal end. Then it was cooled using chloroethane (C_2H_5Cl), straightened, placed on a rod and inserted into the placement catheter. The catheter was inserted into the body organ to be treated with the fixing ring on the straightened nitinol spiral placed in the area of the lower end of the stricture. The spiral, responding to body heat, began to acquire the previously given shape. After the spiral reformed from its low temperature shape, it was disconnected from the placement rod and the rod was removed from the organ."

Applicant respectfully traverses this rejection. The fixing ring does not hold a portion of a sheath to the rod as required in claim 3. Rather the fixing ring holds a nitinol spiral in its straightened shape and is removed so the spiral returns to its spiral shape. The nitinol spiral is not a sheath as claimed in the instant invention.

Although the claims as is are deemed to define over the cited art for the reasons outlined above, for the purposes of clarity claim 1 has been amended to recite the above differences, namely, "wherein said elastomeric sheath surrounds the outside portion of the rod both in the non-expanded and expanded orientations and wherein said folds in the expanded orientation comprise a plurality of crests and troughs". The crests and troughs of the folds are clearly shown in the drawings and do not constitute new matter.

New claim 19 has been introduced reciting further patentable features, namely, "wherein said folds of said sheath are spaced generally equally from each other". This is clearly shown in the drawings and does not add new matter. Accordingly all of the rejections are deemed overcome and claims 1-19 are deemed allowable.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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